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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,169	WENRICH, MARSHALL S.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/04; 10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 11/22/2004 and 10/6/2006 have been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, "said pump" lacks antecedent basis. Note claim 1 is silent with respect to the device including a pump.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 10, 21-25 and 30-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Alford et al.(WO 03/024214 or US 2003/0054540).

With respect to claim 1, the reference of Alford et al. discloses a perfusion loop (See Figure 1) that includes an organ container (8); a bubble remover (11); and an oxygenator (21). With respect to the "disposable after a single use" limitation, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 2, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device and the reference discloses the use of peristaltic pump (24).

With respect to claim 3, the reference discloses the use of temperature regulator (6).

With respect to claim 10, the temperature regulator (6) is in heat-exchange contact with the organ container (8) (See Figure 2).

With respect to claims 21, 25, 31 and 32, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 22, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device. Also, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 23, the reference of Alford et al. discloses the use of pump (24).

With respect to claim 24, any of the components of the device can be disposed of or reused. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 30, the reference of Alford et al. discloses the use of a cover (9) including an adaptor (7) and quick connect-disconnect coupling (5).

6. Claims 1-3, 10, 21-25 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Alford et al.(US 6,677150).

With respect to claim 1, the reference of Alford et al. discloses a perfusion loop (See Figure 1) that includes an organ container (8); a bubble remover (11); and an oxygenator (21). With respect to the "disposable after a single use" limitation, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 2, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device and the reference discloses the use of peristaltic pump (24).

With respect to claim 3, the reference discloses the use of temperature regulator (6).

With respect to claim 10, the temperature regulator (6) is in heat-exchange contact with the organ container (8) (See Figure 2).

With respect to claims 21, 25, 31 and 32, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 22, the reference of Alford et al. discloses the use of tubing (19) to connect the elements of the device. Also, any of the elements listed above are considered to be

capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 23, the reference of Alford et al. discloses the use of pump (24).

With respect to claim 24, any of the components of the device can be disposed of or reused. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 30, the reference of Alford et al. discloses the use of a cover (9) including an adaptor (7) and quick connect-disconnect coupling (5).

7. Claims 1-3 and 5-32 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Owen et al.(US 6,673,594).

With respect to claim 1, the reference of Owen et al. discloses a perfusion loop (See Figures 1 and 2) that includes an organ container (40); a bubble remover (5040); and an oxygenator (110 or 5030). With respect to the "disposable after a single use" limitation, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 2, the reference of Owen et al. discloses the use of tubing (91) to connect the elements of the device and the reference discloses the use of peristaltic pump (90).

With respect to claim 3, the reference discloses the use of temperature regulator (30b).

With respect to claims 5 and 6, the Peltier device (30b) is capable of heating or cooling the perfusion fluid.

With respect to claim 7-9, the reference discloses temperature controller (150) which is capable of being programmed as indicated in the claims.

With respect to claim 10, the temperature regulator (30b) is in heat-exchange contact with the organ container (40) (See Figure 2).

With respect to claims 11 and 12, the reference of Owen et al. discloses that the perfusion system can include a reservoir (10) that includes a temperature regulator (30a).

With respect to claims 13-16, the reference of Owen et al. discloses that the perfusion device can include a processor that can be programmed by the user (See column 13, lines 23-41; and column 15, lines 24-44).

With respect to claims 17-20, the reference of Owen et al. discloses that the perfusion device can include an air venting system that operates in conjunction with a bubble detection and removal system (See column 14, lines 34-61; column 18, lines 11-21).

With respect to claims 21, 25, 31 and 32, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 22, the reference of Owen et al. discloses the use of tubing (91) to connect the elements of the device. Also, any of the elements listed above are considered to be capable of being disposed of after a single use. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 23, the reference of Owen et al. discloses the use of pump (90).

With respect to claim 24, any of the components of the device can be disposed of or reused. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claims 26-29, the reference of Owen et al. discloses that the use of a radio tag and reader are known in the art of organ perfusion (See column 13, lines 23-41).

With respect to claim 30, the reference of Owen et al. discloses the use of a cover (67d) including an adaptor (62) and quick connect-disconnect coupling (64).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of Olympus (JP-01-261301).

The reference of Alford et al. has been discussed above.

Claims 3-9 differ by specifying the use of a specific temperature regulation system that includes heat exchange fluids, tubes and a Peltier device to regulate the temperature of the perfusion loop.

The reference of Olympus discloses that it is known in the art of organ perfusion to employ a coolant (19) in heat exchange communication with the perfusion loop and to employ a Peltier device (15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the temperature control taught by the reference of Olympus in the system of the primary reference for the known and expected result of providing an art recognized means for providing temperature control of the perfusion loop system.

With respect to claim 4, if the tubes of the perfusion loop do not meet this claim, it would have been obvious to one of ordinary skill in the art to provide heat exchange tubes in the system for the known and expected result of increasing the surface area for heat exchange between the perfusion fluid and heat exchange fluid.

With respect to claims 5 and 6, the Peltier device (15) is capable of heating or cooling the perfusion fluid.

With respect to claims 7-9, the system of Olympus discloses the use of a temperature controller (20) which is capable of being programmed as indicated in the claims.

11. Claims 11-20 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alford et al.(WO 03/024214 or US 2003/0054540 or US 6,677,150) in view of Owen et al.(US 6,673,594).

The reference of Alford et al. has been discussed above.

Claims 11 and 12 differ by reciting that the device includes a reservoir with a temperature regulator.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion system with a reservoir (10) that includes a temperature regulator (30a).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a reservoir system as suggested by the reference of Owen et al. for the known and expected result of providing a source of additional perfusion fluid that can be added to the perfusion loop and maintained at the required temperature conditions.

Claims 13-16 differ by reciting that the device includes a processor for controlling the perfusion conditions within the device.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with a processor that can be programmed by the user (See column 13, lines 23-41; and column 15, lines 24-44).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with a processor for the known and expected result of automating the operation of the device.

Claims 17-20 differ by reciting that the device includes a processor controlled venting system.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with an air venting system that operates in conjunction with a bubble detection and removal system (See column 14, lines 34-61; column 18, lines 11-21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with the bubble detection, removal and gas venting

system suggested by the reference of Owen et al. for the known and expected result of automating the removal of gas or bubbles from the perfusion loop.

Claims 26-29 differ by reciting that the device includes a radio frequency identification tag installed on the organ container and associated reader wherein the tag is used to program the control processor.

The reference of Owen et al. discloses that the use of a radio tag and reader are known in the art of organ perfusion (See column 13, lines 23-41).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with a radio tag system suggested by Owen et al. for the known and expected result of providing a means recognized in the art for allowing the organ to be remotely monitored and/or data to be transferred for further use and/or control.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al.(US 6,673,594).

The reference of Owen et al. has been discussed above.

With respect to claim 4, if the tubes of the perfusion loop do not meet this claim, it would have been obvious to one of ordinary skill in the art to provide heat exchange tubes in the system for the known and expected result of increasing the surface area for heat exchange between the perfusion fluid and heat exchange fluid.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-3, 10, 21-25 and 30-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,677,150. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 10, 21-25 and 30-32 are generic to all that is recited in claims 1-25 of U.S. Patent No. 6,677,150. That is, claims 1-25 of U.S. Patent No. 6,677,150 falls entirely within the scope of claims 1-3, 10, 21-25 and 30-32 or, in other words, claims 1-3, 10, 21-25 and 30-32 are anticipated by claims 1-25 of U.S. Patent No. 6,677,150.

15. Claims 3-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,677,150 in view of Olympus (JP-01-261301).

Claims 3-9 differ by specifying the use of a specific temperature regulation system that includes heat exchange fluids, tubes and a Peltier device to regulate the temperature of the perfusion loop.

The reference of Olympus discloses that it is known in the art of organ perfusion to employ a coolant (19) in heat exchange communication with the perfusion loop and to employ a Peltier device (15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the temperature control taught by the reference of Olympus in the system encompassed by the patented claims for the known and expected result of providing an art recognized means for providing temperature control of the perfusion loop system.

With respect to claim 4, if the tubes of the perfusion loop do not meet this claim, it would have been obvious to one of ordinary skill in the art to provide heat exchange tubes in the system for the known and expected result of increasing the surface area for heat exchange between the perfusion fluid and heat exchange fluid.

With respect to claims 5 and 6, the Peltier device (15) is capable of heating or cooling the perfusion fluid.

With respect to claims 7-9, the system of Olympus discloses the use of a temperature controller (20) which is capable of being programmed as indicated in the claims.

16. Claims 11-20 and 26-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,677,150 in view of Owen et al.(US 6,673,594).

Claims 11 and 12 differ by reciting that the device includes a reservoir with a temperature regulator.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion system with a reservoir (10) that includes a temperature regulator (30a).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the patented claims with a reservoir system as suggested by the reference of Owen et al. for the known and expected result of providing a source of additional perfusion fluid that can be added to the perfusion loop and maintained at the required temperature conditions.

Claims 13-16 differ by reciting that the device includes a processor for controlling the perfusion conditions within the device.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with a processor that can be programmed by the user (See column 13, lines 23-41; and column 15, lines 24-44).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the patented claims with a processor for the known and expected result of automating the operation of the device.

Claims 17-20 differ by reciting that the device includes a processor controlled venting system.

The reference of Owen et al. discloses that it is conventional in the art of organ perfusion to provide the perfusion device with an air venting system that operates in conjunction with a bubble detection and removal system (See column 14, lines 34-61; column 18, lines 11-21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the patented claims with the bubble detection, removal and gas venting system suggested by the reference of Owen et al. for the known and expected result of automating the removal of gas or bubbles from the perfusion loop.

Claims 26-29 differ by reciting that the device includes a radio frequency identification tag installed on the organ container and associated reader wherein the tag is used to program the control processor.

The reference of Owen et al. discloses that the use of a radio tag and reader are known in the art of organ perfusion (See column 13, lines 23-41).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the patented claims with a radio tag system suggested by Owen et al. for the known and expected result of providing a means recognized in the art for allowing the organ to be remotely monitored and/or data to be transferred for further use and/or control.

17. Claims 1-32 are directed to the same invention as that of claims 1-25 of commonly assigned 6,677,150. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB